SENATE BILL No. 285

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-42-19; IC 25-26-13-25; IC 34-30-2-84.3.

Synopsis: Prescription drug labels. Provides that a prescription label must include a statement of the purpose or symptom for which the drug is prescribed if the practitioner directs that the statement is to be included. Provides that a practitioner is not liable for failing to inform a patient that the patient has the option to have the purpose or symptom for which the drug is prescribed on the label. Makes a technical correction.

Effective: July 1, 2004.

Ford, Riegsecker

January 8, 2004, read first time and referred to Committee on Health and Provider Services.

Introduced

Second Regular Session 113th General Assembly (2004)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2003 Regular Session of the General Assembly.

SENATE BILL No. 285

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-42-19-11, AS AMENDED BY P.L.239-1999, SECTION 2, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: Sec. 11. (a) Except as provided in section 21 of this chapter, a person may not sell a legend drug unless either of the following conditions exist:

(1) Except as provided in subsection (b), the legend drug is dispensed by a pharmacist upon an original prescription or drug order with the drug product specified on the prescription or drug order or by the authorization of the practitioner and there is affixed to the immediate container in which the drug is delivered a label bearing the following:

(A) The name, address, and phone number of the establishment from which the drug was dispensed.

(B) The date on which the prescription for the drug was filled.

(C) The number of the prescription as filed in the prescription files of the pharmacist who filled the prescription.

(D) The name of the practitioner who prescribed the drug.

(E) The name of the patient, or if the drug was prescribed for an animal, a statement of the species of the animal.

(F) The directions for the use of the drug as contained in the prescription.

(G) The symptom or purpose for which the drug is being prescribed, if included at the practitioner's direction.

(2) The legend drug is delivered by the practitioner in good faith in the course of practice and the immediate container in which the drug is delivered bears a label on which appears the following:

(A) The directions for use of the drug.

(B) The name and address of the practitioner.

(C) The name of the patient.

(D) If the drug is prescribed for an animal, a statement of the species of the animal.

(E) The symptom or purpose for which the drug is being prescribed, if included at the practitioner's direction.

This section does not prohibit a practitioner from delivering professional samples of legend drugs in their original containers in the course of the practitioner's practice when oral directions for use are given at the time of delivery.

(b) Notwithstanding subsection (a)(1), the following apply:

(1) A pharmacist at a hospital licensed under IC 16-21 may fill a drug order for a legend drug with a drug product allowed under the hospital's policies and procedures for the use, selection, and procurement of drugs.

(2) A pharmacist who fills a prescription for a legend drug must comply with IC 16-42-22 and IC 25-26-16.

SECTION 2. IC 16-42-19-20.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: **Sec. 20.5. (a) After advising a patient that the patient may authorize the prescription or drug order label to include the symptom or purpose for which a prescription or drug order is being issued, the practitioner may direct that a written statement of the symptom or purpose for which a prescription or drug order is being issued is to be included on the prescription or drug order label.**

(b) A practitioner's failure to advise a patient under subsection (a):

(1) is not grounds for disciplinary sanctions or a civil action against the practitioner; and

(2) may not be used as evidence in a civil action against the practitioner.

SECTION 3. IC 16-42-19-27 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: Sec. 27. (a) A person who knowingly violates this chapter, except sections **20.5,** 24, and 25(c) of this chapter, commits a Class D felony. However, the offense is a Class C felony if the person has a prior conviction under this subsection or IC 16-6-8-10(a) before its repeal.

(b) A person who violates section 24 of this chapter commits a Class B misdemeanor.

(c) A person who violates section 25(b) of this chapter commits dealing in an anabolic steroid, a Class C felony. However, the offense is a Class B felony if the person delivered the anabolic steroid to a person who is:

(1) less than eighteen (18) years of age; and

(2) at least three (3) years younger than the delivering person.

SECTION 4. IC 25-26-13-25, AS AMENDED BY P.L.182-2003, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. The files shall be open for inspection to any member of the board or its duly authorized agent or representative.

(b) Except as provided in subsection (c), ~~before the expiration of subsection (c) on June 30, 2003,~~ a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written or oral authorization of a licensed practitioner.

(c) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would

otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (f).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (d).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum

amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill".

(d) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(e) The original prescription form or the other board approved record described in subsection (d) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(6) The symptom or purpose for which the drug is being prescribed, if included at the practitioner's direction.

(f) A prescription is valid for not more than one (1) year after the original date of issue.

(g) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(h) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(i) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to a patient residing in an institutional facility (as defined in 856 IAC 1-28-1(a));

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper

resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as described in IC 25-26-13-17).

(j) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under subsection (i).

(k) A pharmacist who violates subsection (c) commits a Class A infraction.

SECTION 5. IC 34-30-2-84.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: **Sec. 84.3. IC 16-42-19-20.5 (Concerning a health practitioner who does not advise a patient concerning the inclusion of a statement of symptom or purpose on a prescription label).**